APR 3 2013

K123829

Traditional 510(k) Summary

A) Submitted by:

Portable Therapeutix
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Contact:

Sharyn Orton, Ph.D.
MEDIcept, Inc.
200 Homer Ave
Ashland, MA 01721
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B) Classification Name: Massager, Powered Inflatable Tube – Product code IRP
Pack, Cold, Reusable – Product code IME

Common Name: Powered inflatable tube massager
Cold Pack

Proprietary Name: Portable Therapeutix Squid Active Cold Compression device and Cold Pack

Device Regulations: and Class: 21 CFR 890.5650, Class II
21 CFR 890.5700, Class I 510(k) exempt

Product Codes: IRP; IME

C) Predicates: K030437 Relaxor Perfect Touch Air Massaging System, Salton, Inc., product code IRP
K112479 DSJ Massager, Mego Afek, product code IRP

D) Device Description:

The Squid Active Cold Compression device and Cold Pack combines intermittent compression with cold therapy. The Squid simulates kneading and stroking of tissues using an inflatable garment attached to a gel ice pack and connected to a pre-programmed air pump. The Squid may be used for the leg, foot, feet, arm, shoulders, lower back, and hands.

The device is manufactured with the following components:

1. A portable external pump-controller unit containing the pneumatic compressor (air pump) that may be run on AC-DC external power supply or a built-in lithium battery.

2. A wrap that contains an air bladder with sequential compression capability and Velcro attachments for the cold pack. The wrap connects to the pump controller via a flexible tube. There may also be an accessory piece to the wrap to provide an additional securing mechanism. Wraps come in two configurations and three sizes.
3. Reusable thermogel cold pack

E) Intended Use/Indication for Use:

The Squid Active Cold Compression device and Cold Pack is indicated for the temporary relief of minor muscle aches and pains.

The compression device is indicated for temporary increase in circulation of the treated areas in people who are in good health, and simulates kneeding and stroking of tissues using an inflatable garment.

The cold pack is indicated for localized therapy in situations where a physician determines that cold temperature therapy is necessary or desirable.

F) Comparison to Predicate Device(s):

	Portable Therapeutix Squid Active Cold Compression device and Cold Pack	**Salton, Inc. Relaxor Perfect Touch Air Massaging System** **K030437**	**Mego Afek DJS Massager** **K112479**
Product code	IRP; IME	IRP	IRP
Intended Use/Indication for Use	The Squid Active Cold Compression device and Cold Pack is indicated for the temporary relief of minor muscle aches and pains. The compression device is indicated for temporary increase in circulation of the treated areas in people who are in good health, and simulates kneeding and stroking of tissues using an inflatable garment. The cold pack is indicated for localized therapy in situations where a physician determines that cold temperature therapy is necessary or desirable.	The Perfect Touch Air Massaging System is indicated for the temporary relief of minor muscle aches and pains and for temporary increase in circulation to the treated areas in people who are in good health. The Perfect Touch simulates kneading and stroking of tissues by using an inflatable garment.	The DJS Massager is indicated for the temporary relief of minor muscle aches and pains and for temporary increase in circulation to the treated areas in people who are in good health. The DJS Massager simulates kneading and stroking of tissues by using an inflatable garment.
Target	Leg, foot, arm, shoulders, lower back, hands	Leg & foot, feet, arm, neck and shoulders, lower back, hands	Boot, leg, arm/shoulder

	Portable Therapeutix Squid Active Cold Compression device and Cold Pack	**Salton, Inc. Relaxor Perfect Touch Air Massaging System** **K030437**	**Mego Afek DJS Massager** **K112479**
Principle of Operation/ Mechanical characteristics	Intermittent compression 4 intensity settings (modes) 1 – 30 mm Hg 2 – 50 mm Hg 3 – 70 mm Hg 4 – 85 mm Hg	Intermittent compression 6 intensity settings 1 – 80 mm Hg 2 – 104 mm Hg 3 – 128 mm Hg 4 – 152 mm Hg 5 – 176 mm Hg 6 – 200 mm Hg	Intermittent compression 3 intensity settings Light - 20-30 mm Hg Medium – 40-60 mm Hg Intense – 70 – 80 mm Hg
Pressure range	0 – 85 mm Hg	0 -200 mm Hg	20 – 80 mm Hg
Total treatment time	15 minutes	15 minutes	30 – 45 minutes
Biocompatible	Nylon with TPU backing wrap- yes	Nylon with TPU backing wrap- yes	To be used over cotton cloth clothing
Pressure control	Microprocessor and pressure sensor	Microprocessor	Not specified
Inflation by	Pressurization pump	Pressurization pump	Pump
Deflation by	Exhaust valve	Exhaust valve	Exhaust vent
Power source	120V 60 Hz, consumption 26W; AC adapter: 120V 60 Hz, consumption 36W Lithium battery	120V 60 Hz, consumption 26W; AC adapter: 120V 60 Hz, consumption 36W No battery	115V ~60 Hz; consumption 2W No battery
Cold Pack	Yes	No	No

Substantial Equivalence Discussion

The Portable Therapeutic Active Cold Compression device and Cold Pack has the same intended use, similar target treatment areas, and similar mechanical intermittent compression as the predicate devices. Pressure intensities are for patient comfort only, and differences do not raise new issues of safety or effectiveness. The addition of a cold pack also does not raise new issues of safety or effectiveness.

Performance

No performance standards have been promulgated for this device.
Bench and EMC testing has been conducted.

Conformity to Standards

There are no FDA recognized consensus standards for this device.

This device complies with IEC 60601-1:1988 + A1:1991 + A2:1995 Medical Electrical Equipment - Part 1: General Requirements for Safety, 1988; Amendment 1, 1991-11, Amendment 2, 1995

Conclusion

The Portable Therapeutix Squid Active Cold Compression device and Cold Pack is substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

April 3,2013

Portable Therapeutix LLC
% Sharyn Orton, Ph.D.
MEDIcept, Inc.
200 Homer Ave.
Ashland, MA 01721

Re: K123829
Trade/Device Name: Squid Active Cold Compression Device and Cold Pack
Regulation Number: 21 CFR 890.5650
Regulation Name: Powered Inflatable Tube Massager
Regulatory Class: Class II
Product Code: IRP, IME
Dated: February 27, 2013
Received: February 28, 2013

Dear Dr. Orton:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Victor Krauthamer -S

Victor Krauthamer, Ph.D.
Acting Director
Division of Neurological
and Physical Medicine Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K123829

Device Name: **Portable Therapeutix Squid Active Cold Compression device and Cold Pack**

Indications for Use:

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The compression device is indicated for temporary increase in circulation of the treated areas in people who are in good health, and simulates kneeding and stroking of tissues using an inflatable garment.

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Prescription Use ___X___ AND/OR Over-the-Counter Use _____
(21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NECESSARY)

Concurrence of CDRH, Office of Device Evaluation and Safety (ODE)

Victor Krauthamer -S
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Division of Neurological and
Physical Medicine Devices
510(k) Number: K123829